UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BRIDGET ENGLISH, KAMMIE MINCHER, and ANGEL SCOTT,

Plaintiffs,

v.

BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., and BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendants.

DECISION AND ORDER

19-CV-6615L

Plaintiffs, former users of the "Essure" medical device, bring this action against defendants, who manufactured and marketed it. Defendants now move (Dkt. #7) to dismiss the complaint pursuant to Fed. R. Civ. Proc. 12(b)(6), and for an award of sanctions and fees against plaintiff Angel Scott ("Scott") pursuant to Fed. R. Civ. Proc. 41 (Dkt. #8). Plaintiffs oppose both motions, and have cross moved to amend the complaint (Dkt. #17). For the reasons that follow, defendants' motion to dismiss is granted, defendants' motion for sanctions is denied, and plaintiffs' cross motion to amend the complaint is denied.

FACTUAL AND PROCEDURAL BACKGROUND

Between 2009 and 2011, the three plaintiffs were each implanted with the Essure birth control device. The device consists of two "micro-inserts" in the form of metal coils, placed in the fallopian tubes under hysteroscopic (camera) guidance. The coils are intended to elicit tissue growth to block the fallopian tubes and thus prevent pregnancy. Plaintiffs allege, however, that

Essure devices have the potential to "migrate" from the fallopian tubes, damaging internal organs and causing "mental health issues and autoimmune diseases." (Dkt. #1 at ¶19).

Plaintiffs assert causes of action for: negligent training of physicians, breach of express warranty and negligent misrepresentation (in the form of advertising concerning safety and effectiveness at preventing pregnancy, and qualifications of implanting physicians), negligent risk management (failing to report adverse events to the FDA), and negligent failure to warn. Although plaintiffs do not specify the injuries that each of them incurred individually, they claim that as a result of defendants' acts and omissions, one or more of them suffered from a laundry list of alleged maladies, including: anxiety, agoraphobia, depression, insomnia, panic attacks, joint and back pain, migraine headaches, lesions and rashes, receding gums, tooth decay, fibromyalgia, excessive bleeding, miscarriages, pregnancies,[1] and "skin falling off of [their] genital area[s]." (Dkt. #1 at ¶105).

DISCUSSION

I. Standard on a Motion to Dismiss

In deciding a motion to dismiss under Fed. R. Civ. Proc. 12(b)(6) for failure to state a cause of action, a court should "draw all reasonable inferences in [a plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted). In evaluating a motion to dismiss, the Court's consideration is generally limited to the pleadings, and to any documents attached or incorporated therein by

[1] While the occurrence of pregnancies and miscarriages during a party's use of the Essure birth control device would seem to be a significant component of damages, the complaint does not contain any additional mention of such outcomes, or any further explanation concerning the damages suffered by the plaintiffs. This lack of specificity complicates efforts to assess whether the complaint states plausible causes of action.

reference. *See Baird v. Kingsboro Psychiatric Ctr.*, 2013 U.S. Dist. LEXIS 153701 at *6-*7 (E.D.N.Y. 2013).

II. Preemption of Plaintiffs' Claims

Defendants principally argue that plaintiffs' claims are entirely preempted by the Medical Device Amendments ("MDA") to the federal Food Drug and Cosmetic Act ("FDCA"). The MDAs grant exclusive authority to the FDA to regulate medical devices, and create a "regime of detailed federal oversight" which expressly preempts any state-law claim or private party lawsuit that would impose safety or effectiveness requirements beyond those imposed by the FDA though its premarket approval ("PMA") process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (finding that a consumer's negligence, strict liability, and implied warranty claims concerning medical devices regulated through the PMA process are barred by the MDA's preemption clause).

The Supreme Court has examined and defined "the contours of federal pre-emption" under §360k(a) of the MDA. *Barone v. Bausch & Lomb*, 372 F.Supp.3d 141, 147 (W.D.N.Y. 2019) (citing *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 247-48 (S.D.N.Y. 2013)). First, in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Supreme Court "held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA rather than on some independent state law duty." *Buckman*, 531 U.S. at 341 at 349. Subsequently, in *Riegel*, 552 U.S. 312, the Court noted that "[s]tate [law requirements and related causes of action] are pre-empted under the MDA *only* to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." 552 U.S. 312 at 330 (quoting 21 U.S.C. § 360k(a)(1))(emphasis added). As such, the MDA preemption provision "does not prevent a State from providing a damages remedy for claims premised on the violation of FDA regulations, [where] 'the state duties in such a case

"parallel," rather than add to, federal requirements.'" *Id*. Vague or generalized allegations of a parallel claim are insufficient, however: there must be a specific state law statutory remedy, or recognized state law duty or obligation.

Subsequently, courts have interpreted *Riegel* and *Buckman* as "creat[ing] a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). "The plaintiff must be suing for conduct that violates the FDCA (or else h[er] claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA ([as] such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic Inc.*, 623 F.3d 1200 at 1204 (quotation and emphasis omitted). "In other words, the plaintiff's state-law claim must 'parallel[ ] a federal-law duty under the MDA' but also exist 'independent[ly]' of the MDA." *A.F. v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (quoting *Stengel v. Medtronic Inc*., 704 F.3d 1224, 1233 (9th Cir. 2013)).

Initially, there is no dispute here that Essure is a "Class III" device, regulated by the MDA, subject to PMA procedures, and granted PMA by the FDA. As such, suits by private parties concerning its use will generally be preempted. *See Buckman*, 531 U.S. 341 at 349 n.4 (all actions to enforce FDA requirements "shall be by and in the name of the United States") (quoting 21 U.S.C. §337(a)).

For this reason, multiple federal and state courts nationwide have previously dismissed, on express and/or implied preemption grounds, claims involving the Essure device which are nearly identical to those asserted by plaintiffs. *See Olmstead v. Bayer Corp.*, 2017 U.S. Dist. LEXIS 129222 (N.D.N.Y. 2017) (dismissing Essure-related claims for negligent misrepresentation, strict liability, failure to warn, and breach of express and implied warranties, as preempted); *Burrell v.*

Bayer Corp., 260 F. Supp. 3d 485 (W.D.N.C. 2017) (dismissing Essure-related claims of negligent failure to warn and breach of express and implied warranties, as preempted); *Norman v. Bayer Corp.*, 2016 U.S. Dist. LEXIS 96993 (D. Conn. 2016) (dismissing, on preemption grounds, Essure-related claims including failure to warn, negligent training, negligent misrepresentation and breach of express warranty); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 603 (Mo. Ct. App. 2017) (affirming the dismissal of Essure-related claims on preemption grounds, including fraudulent and negligent misrepresentation, breach of express and implied warranties, failure to warn, and negligent training). The Court finds no reason to depart from this consistent and well-settled precedent.

With respect to plaintiffs' negligent training claims, plaintiffs allege that the defendants breached their duty to train physicians in numerous ways. First, plaintiffs allege that defendants failed to properly train physicians in hysteroscopy, failed to sufficiently supervise physicians during placement procedures, and failed to monitor patients thereafter. However, they do not plausibly allege that the FDA-approved training requirements placed any duty on defendants to do so. "To therefore place upon Bayer a duty to provide this training [or monitoring] would be imposing a requirement 'different [from], or in addition to,' what is required by the FDA," and accordingly, such claims are expressly preempted. *Williams*, 541 S.W.3d 594 at 611 (quoting *Riegel*, 552 U.S. 312 at 323-25).

To the extent that plaintiffs claim that defendants did deviate from FDA-approved training requirements by failing to ensure that implanting physicians completed preceptoring requirements, read and understood the Physician Training Manual, and successfully completed simulator training, such claims do not seek to impose obligations beyond those mandated by the FDA, and thus are arguably not expressly preempted. However, they are nonetheless impliedly preempted:

plaintiffs have not pled any parallel state law cause of action that supports their negligent training claims, nor does their opposition to the instant motion identify any New York law establishing liability on the part of a non-employer for injuries to third parties arising out of alleged negligent training. *See generally Norman*, 2016 U.S. Dist. LEXIS 96993 at *13 (an Essure-related negligent training claim requires a parallel state law cause of action in order to escape implied preemption). For this reason, plaintiffs' reliance on *McLaughlin v. Bayer Corp.*, 2017 U.S. Dist. LEXIS 24378 (E.D.Pa. 2017), wherein the district court for the Eastern District of Pennsylvania found that certain Essure-related claims including failure to train were not expressly preempted because they sought to enforce FDA-imposed obligations, and furthermore were not impliedly preempted because they were cognizable as parallel claims under Pennsylvania state law, is misplaced. Because there is no comparable New York law pursuant to which plaintiffs can assert or pursue negligent training claims (nor do plaintiffs make any attempt to identify any), *McLaughlin* is neither squarely applicable nor controlling here.[2]

With respect to plaintiffs' "failure to report adverse events to the FDA" claims, if they are characterized as a failure to warn, they are expressly preempted: plaintiffs cannot maintain a claim that defendants were required to issue additional warnings beyond what the FDA prescribed and approved. Furthermore, as a standalone claim, "failure to report adverse events to the FDA" is not a cognizable cause of action under New York law. *See Mitaro v. Medtronic, Inc.*, 73 A.D.3d 1142, 1142-43 (N.Y. App. Div. 2nd Dep't 2010). *See also Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 201-202 (E.D.N.Y. 2015) ("[w]hile New York law may require manufacturers to warn the medical profession, that is not the same as a duty to report to the FDA"). *Accord*

[2] In fact, plaintiffs' entire treatment of defendants' 25-page memorandum emphasizing the preemption argument is contained in a single paragraph which cites to *McLaughlin* (which applied Pennsylvania law), with no analysis whatsoever of its applicability in New York. (Dkt. #7-21, #17-12 at 8).

Norman, 2016 U.S. Dist. LEXIS 96993 at *9-*10 (failure to warn claims premised on failure to warn the FDA by reporting adverse events are preempted); *Richardson v. Bayer Healthcare Pharms*., 2016 U.S. Dist. LEXIS 117702 at *19 (D. Id. 2016) (failure to warn claims based on failure to report adverse events to the FDA are preempted unless plaintiffs can show the existence of a parallel state law requirement that can be used to enforce that duty). Although plaintiffs alternatively allege that failure to report adverse events supports a claim for "negligent risk management," plaintiffs identify no state law supporting the existence of such a cause of action in New York.

Finally, plaintiffs' misrepresentation and breach of express warranty claims do not cite to any labeling or advertising that is so inconsistent with FDA-approved language as to be false or misleading. "[W]hether volunteered by the manufacturer or required by law, claims based on written or oral statements whose content falls within the parameters of FDA-approved labeling are expressly preempted under the MDA." *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 224 (W.D.N.Y. 2016).

Although plaintiffs point to numerous differences in verbiage between the FDA-approved labeling of Essure and defendants' own representations (e.g., FDA-approved labeling that Essure "acutely anchors . . . result[ing] in . . . device retention," vs. defendants' statement that "Essure inserts stay secure," or FDA-approved labeling of Essure as offering "peace of mind" vs. defendants' statements that Essure is "worry-free"), plaintiffs have not identified any statements by defendants that substantively stray beyond those approved by the FDA. *See generally Williams*, 541 S.W.3d 594, 603 (dismissing fraudulent and negligent misrepresentation claims on preemption grounds where the challenged statements "were functionally equivalent to those in the Essure labeling approved by the FDA"); *Norman*, 2016 U.S. Dist. LEXIS 96993 at *15 (D. Conn.

2016) (finding that statements concerning Essure's safety and effectiveness, and a promise to "sign off" on hysteroscopy training for physicians, are "so similar to the approved language as to be substantively the same").

In sum, plaintiffs' attempts to distinguish their claims to bring them outside of the scope of the preemption provisions of the Medical Device Amendments to the FDCA, or otherwise to state plausible parallel claims under the laws of New York State, are unavailing.[3] Plaintiffs' claims of negligent misrepresentation, breach of express warranty, failure to warn, negligent risk management, and negligent training, are accordingly dismissed.

Having determined that plaintiffs' claims are subject to dismissal on the foregoing grounds, the Court declines to consider the alternative bases for dismissal presented by defendants in support of the instant motion, including but not limited to the complaint's failure to comply with the pleading requirements of Fed. R. Civ. Proc. 8.

III. Plaintiffs' Cross Motion to Amend the Complaint

Along with opposing the instant motion to dismiss the complaint, plaintiffs have cross moved (Dkt. #17) to amend it.

Generally, a "court should freely give leave [to amend] when justice so requires." Fed. R. Civ. Proc. 15. "Where it appears that granting leave to amend is unlikely to be productive, however, it is not an abuse of discretion to deny leave to amend." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 62 (2d Cir. 2016) (quoting *Ruffolo v. Oppenheimer & Co.*, 987 F.2d 129, 131 (2d Cir. 1993)).

[3] Plaintiffs' opposition papers also attempt to defend claims of negligent manufacturing and fraudulent misrepresentation. These claims are not asserted, identified or otherwise stated in plaintiffs' complaint, and as such, the Court will disregard these arguments as moot.

Initially, plaintiffs' motion to amend does not comply with the applicable Local Rule, which requires that amendments and supplements to a proposed amended pleading be identified through redlining or similar markings. W.D.N.Y. Local Rules of Civ. Proc., Rule 15(b).

Notwithstanding this deficiency, the Court has considered the motion on its merits. The proposed amended complaint (Dkt. #17-2) appears to be largely identical to plaintiffs' original complaint, except that it: (1) adds a cause of action for fraudulent misrepresentation, based upon the same facts and statements that formed the basis of the original complaint's cause of action for negligent misrepresentation, and thus equally preempted; and (2) includes a number of extraneous factual allegations which appear to have been cut-and-pasted from a pleading in an unrelated case.[4]

Because the claims contained in the amended complaint would be subject to dismissal as preempted and/or insufficiently stated for the reasons set forth above, amendment would be futile. Plaintiffs' motion to amend the complaint is therefore denied.

IV. Motion Pursuant to Fed. R. Civ. Proc. 41(d)

Defendants have also requested an order of sanctions against plaintiff Scott pursuant to Rule 41(d) of the Federal Rules of Civil Procedure, which provides that "a plaintiff who previously dismissed an action in any court," who subsequently "files an action [for] the same claim against the same defendant," may be ordered to pay the costs of the prior proceeding, and their subsequent

[4] The Court concurs with defendants' troubling observation that the 94-page proposed amended complaint not only fails to meaningfully correct the deficiencies contained in the first, but to the extent that it presents new material, some of that material appears to have been cut-and-pasted, without editing, from one of the pleadings in *McLaughlin v. Bayer Corp., supra*. Specifically, the proposed amended complaint contains verbatim allegations and descriptions of injuries (all attributed to a singular plaintiff instead of the three plaintiffs to this action) that conflict with the facts alleged in the original complaint in this case, but match the allegations in *McLaughlin*. Emphasizing its true origin, the proposed amended complaint even includes an allegation that "the plaintiff" saw certain warranties made by defendants from her home, located at a particular street address in Connellsville, Pennsylvania – in actuality, the home address of the *McLaughlin* plaintiff. (Dkt. #17-2; #20 at 3-5). In contrast, the plaintiffs in this action, according to both the original and proposed amended complaints, are all residents of New York State. In light of these flaws, it is difficult to take plaintiffs' proposed amended complaint seriously.

action may be stayed pending their compliance with the order awarding costs. Fed. R. Civ. Proc. 41(d).

Defendants contend that Scott already filed, and later voluntarily dismissed, an action based on the same nexus of facts as those presented here (albeit asserting different claims, such as defective manufacturing) in Wayne County Supreme Court in 2018. They note that their counsel performed substantial work in that matter, including preparation of a motion to dismiss the complaint. They ask that Scott be ordered to pay their costs and attorneys fees from the prior action, and request that proceedings in the instant matter be stayed until she complies.

In determining whether a second action is "based on or include[es] the same claim against the same defendant," courts may consider whether the second suit is "predicated on the same facts." *Ramirez v. iBasis, Inc*., 2010 U.S. Dist. LEXIS 27690 at *9 (E.D.N.Y. 2010). The fact that two actions involve different theories of recovery or distinct forms of relief "is not dispositive for Rule 41(d)." *Horowitz* v. *148 South Emerson Assocs. LLC*, 888 F.3d 13, 23-24 (2d Cir. 2018).

When awarding costs, the court may also consider the plaintiff's motives in dismissing the prior case. *Preferred Freezer Servs., LLC v. Americold Realty Trust*, 2020 U.S. Dist. LEXIS 27495 at *7 (S.D.N.Y. 2020). "[E]ven though a defendant need not show that a plaintiff acted in bad faith in order to recover, a district court may refuse to impose [Rule 41(d) costs] on the plaintiff if it appears that there was a good reason for the dismissal of the prior action or that the plaintiff financially is unable to pay the costs." *Id.*, 2020 U.S. Dist. 27495 at *7-*8 (internal quotation marks and citations omitted). "Rule 41(d)'s purpose is clear and undisputed: to serve as a deterrent to forum shopping and vexatious litigation." *Horowitz*, 888 F.3d 13 at 25 (internal quotation marks and citation omitted).

Scott concedes that she filed and dismissed a prior suit against defendants, suggesting that she or her attorney failed to adequately investigate her claims before filing the 2018 lawsuit, and that she later decided she preferred to litigate in a forum with the opportunity for multidistrict litigation. However, she asks the Court not to award sanctions, because she is indigent, and has supported her contention with a copy of a duly sworn Poor Person Affidavit that was filed in connection with the prior action on or about October 18, 2018. (Dkt. #17-11).

While Scott's tactics clearly fall within the scope of duplicative litigation that Fed. R. Civ. Proc. 41(b) is designed to address, involving nearly identical defendants and the same nexus of operative facts, the Court finds that Scott has sufficiently established that she is financially unable to pay the defendants' costs associated with the prior action. *See generally Gregory v. Dimock*, 286 F.2d 717 (2d Cir. 1961) (granting writ of mandamus and ordering district court to expunge order granting costs and a stay pursuant to Fed. R. Civ. Proc. 41, where plaintiff's indigence prevented payment). The Court accordingly declines to award sanctions at this juncture, but cautions Scott that the filing of any additional actions against the same parties, based on the same operative facts, could result in reexamination of the above factors, with the potential for imposition of monetary and other sanctions.

CONCLUSION

For the reasons stated above, defendants' motion to dismiss the complaint (Dkt. #7) is granted, and the complaint is dismissed in its entirety, with prejudice. Plaintiffs' cross motion to amend the complaint (Dkt. #17) is denied. Defendants' motion seeking sanctions against plaintiff Angel Smith (Dkt. #8) is denied.

IT IS SO ORDERED.

DAVID G. LARIMER
United States District Judge

Dated: Rochester, New York
June 25, 2020